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On November 6, 2003
By: Angela R.

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Attorney Docket No.: 023070-138220US **PATENT**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Michael German *et al.*

Application No.: 09/811,323

Filed: March 16, 2001

For: DELIVERY OF THERAPEUTIC
GENE PRODUCTS BY
INTESTINAL CELL EXPRESSION

Examiner: Dave Trong Nguyen

Art Unit: 1632

**DECLARATION UNDER
37 C.F.R. § 1.131**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We, Michael S. German, Associate Professor of Medicine at the University of California, San Francisco (UCSF); Stephen Rothman, Professor of Stomatology and Physiology at UCSF; and Ira D. Goldfine, Professor in Residence of Medicine and Physiology at UCSF, state as follows:

1. We are co-inventors of the invention claimed in U.S. Patent Application No. 09/811,323, filed March 16, 2001 (herein "the '323 Application"), which claims priority to U.S. Patent Application No. 08/717,084, filed September 20, 1996.
2. The invention disclosed and claimed in the '323 Application is directed to, *inter alia*, methods of delivering a secreted protein to the bloodstream by intestinal cell expression of a foreign gene encoding the protein. In one embodiment of our invention, the method comprises the following steps: